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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,797

Applicant(s)

LANGLOIS ET AL.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 41-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-40 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/18/05 8/19/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-40 in the reply filed on July 27, 2006 is acknowledged.
2. Claims 41-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 27, 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "small" in claim 27 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what diameter sizes would be considered small, rendering the claim indefinite.

Claim Rejections - 35 USC § 102

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 8, 9, 11-13, 21-23, 27, 28, 31-34, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Miles et al. [US 6,576,459].

With respect to claim 1, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28), a filtering device sensitive to density and size differences between particles (column 4, lines 30-35), and mixing the particles with antibody coated beads using an ultrasonic mixer (sample preparation means) (column 4, lines 40-45) for analysis by a detector (flow cytometer, column 4, lines 63-65).

8. With respect to claim 2, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28).

9. With respect to claims 3-4, Miles et al. teach a filtering device sensitive to density and size differences between particles, wherein large particles and dense particles will be transferred to waste (column 4, lines 30-35).

10. With respect to claim 8, Miles et al. teach subjecting the particles to an immunoassay with the use of antibody coated beads (column 4, lines 42-45), which would require an immunoassay sample.

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11. With respect to claim 9, Miles et al. teach that the particles can be subjected to a PCR assay (nucleic acid assay, column 4, lines 35-42), which would require a nucleic acid sample.
12. With respect to claim 11, Miles et al. teach a filtering device sensitive to density and size differences between particles (column 4, lines 30-35),
13. With respect to claim 12, Miles et al. teach an ultrasonic fractionation device (lysing means, column 4, lines 30-32, 55-65).
14. With respect to claim 13, Miles et al. teach an ultrasonic mixer (column 4, lines 40-45).
15. With respect to claims 21-23, Miles et al. teach subjecting the particles to an immunoassay with the use of antibody coated beads (column 4, lines 42-45).
16. With respect to claim 27, Miles et al. teach 1-10 μm sized polystyrene beads (column 3, lines 28-31).
17. With respect to claim 29, 31-34, 40, Miles et al. teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector.
18. Claims 1-2, 10, 11, 13-18, 20, 33, 37-39 are rejected under 35 U.S.C. 102(e) and under 35 U.S.C. 102(a) as being anticipated by Wick [US 6,491,872].

With respect to claim 1, Wick teaches a system and method for detecting the presence of submicron sized particles in a sample taken from the environment includes a collecting a sample from the environment (collector) and purifying and concentrating the submicron particles in a sample based on the size of the particles (sample preparation means) (abstract). The purified and concentrated particles are detected with an apparatus which includes an electrospray assembly

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having an electrospray capillary, a differential mobility analyzer which receives the output from the capillary, and a condensation particle device for counting the number of particles that pass through the differential mobility analyzer (detector) (abstract).

19. With respect to claim 2, a collector is used for aerosol or gaseous fluid sampling (column 5, lines 5-10).

20. With respect to claims 10-11, Wick teaches that the system is capable of purifying and concentrating the submicron particles in a sample based on the size of the particles (abstract).

21. With respect to claims 13, Wick teaches a mixed MS2 sample (column 19, lines 28-31), which would require a mixing means.

22. With respect to claims 14, 20 Wick teaches a means for injecting a sample (electrospray unit, column 19, lines 8-11), means for adding a reagent to the sample (sample solutions for removing contaminants and retain viruses of interest, column 19, lines 15-18), means for mixing the sample and the reagent (resulting in a mixed MS2 sample, column 19, lines 28-31), and means for transporting the sample and reagent (column 2, lines 65-67).

23. With respect to claims 15, 16, Wick teaches that the sample liquid and displacement fluid are sequentially pumped (sequential injection analysis system) (column 6, lines 45-55) in a continuous flow operation (flow injection analysis system) (column 6, lines 55-60).

24. With respect to claim 17, Wick teaches a mixing valve (column 7, lines 15-20).

25. With respect to claim 18, Wick teaches a valve with multiple positions (column 10, lines 55-60).

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26. With respect to claim 33, Wick teaches a condensation particle device for counting the number of particles that pass through the differential mobility analyzer (confirmation means) (abstract).

27. With respect to claims 37-39, Wick teaches a means for injecting a sample (electrospray unit, column 19, lines 8-11), means for adding a reagent to the sample (sample solutions for removing contaminants and retain viruses of interest, column 19, lines 15-18), means for mixing the sample and the reagent (resulting in a mixed MS2 sample, column 19, lines 28-31), and means for transporting the sample and reagent (column 2, lines 65-67), which one of ordinary skill in the art would realize would be capable to use in PCR amplification.

28. Claims 1, 11, 14-20, 33, 36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Colston, Jr. et al. [US 2003/0032172].

With respect to claim 1, Colston, Jr. et al. teach a nucleic acid assay system for analyzing a sample (other substance) using a reagent comprising a holding means that receives the sample and the reagent, a PCR reactor means that amplifies the sample and produces an amplified sample, a detection means detects PCR amplicon, a transport means selectively transports the sample, the reagent, and the amplified sample relative to the holding means, the PCR reactor means, and the detection means, wherein the transport means is operatively connected to the holding means, the PCR reactor means, and the detection means (para. 0019). Colston, Jr. et al. further teach control means is provided for selectively adding the reagent to the sample, mixing the sample and the reagent, performing PCR amplification, and detecting PCR amplicon and a decontamination means is provided for decontaminating the holding means, the PCR reactor means, and the detection means (para.0019).

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29. With respect to claim 11, Colston, Jr. et al. teach that the PCR amplification process includes purification process (para. 0016).

30. With respect to claim 14, Colston, Jr. et al. teach a nucleic acid assay system for analyzing a sample (other substance) using a reagent comprising a holding means that receives the sample and the reagent, a PCR reactor means that amplifies the sample and produces an amplified sample, a detection means detects PCR amplicon, a transport means selectively transports the sample, the reagent, and the amplified sample relative to the holding means, the PCR reactor means, and the detection means, wherein the transport means is operatively connected to the holding means, the PCR reactor means, and the detection means (para. 0019). Colston, Jr. et al. further teach control means is provided for selectively adding the reagent to the sample, mixing the sample and the reagent, performing PCR amplification, and detecting PCR amplicon and a decontamination means is provided for decontaminating the holding means, the PCR reactor means, and the detection means (para.0019).

31. With respect to claim 15, Colston, Jr. et al. teach a sequential injection analysis system (para. 0036).

32. With respect to claim 16, Colston, Jr. et al. teach a means for injecting and or aspirating a sample provides injection and/or aspiration of the sample (para. 0041).

33. With respect to claims 17, 18, Colston, Jr. et al. teach a multi-position valve (para. 0037).

34. With respect to claim 19, Colston, Jr. et al. teach a super serpentine reactor (para. 0047).

35. With respect to claim 20, Colston, Jr. et al. teach mixing means (para. 0039) and transport means (para. 0019).

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36. With respect to claims 33, 36, Colston, Jr. et al. teach real time PCR detection (para. 0055).

37. With respect to claim 37, Colston, Jr. et al. teach a PCR reactor means that amplifies the sample and produces an amplified sample (para. 0019).

38. With respect to claims 38-39, Colston, Jr. et al. teach a nucleic acid assay system for analyzing a sample using a reagent comprising a holding means that receives the sample and the reagent, a PCR reactor means that amplifies the sample and produces an amplified sample, a detection means detects PCR amplicon, a transport means selectively transports the sample, the reagent, and the amplified sample relative to the holding means, the PCR reactor means, and the detection means, wherein the transport means is operatively connected to the holding means, the PCR reactor means, and the detection means (para. 0019). Colston, Jr. et al. further teach control means is provided for selectively adding the reagent to the sample, mixing the sample and the reagent, performing PCR amplification, and detecting PCR amplicon and a decontamination means is provided for decontaminating the holding means, the PCR reactor means, and the detection means (para.0019).

39. Claims 1-5, 7, 9-11, 32, 33, 35-37 rejected under 35 U.S.C. 102(e) as being anticipated by Daugherty et al. [US 2004/0028561].

With respect to claim 1, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles in on and around mail (substance being monitored), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-

hazardous particles, and an analysis subsystem for determining the composition of the biohazardous particles in the analysis sample (para. 0007).

40. With respect to claim 2, Daugherty et al. teach a concentrating the particles using a conventional aerosol concentrator (para. 0032).

41. With respect to claims 3, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles from collected particles for testing (para.007).

42. With respect to claims 4, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles (separation based on predetermined size) from collected particles for testing (para. 0007).

43. With respect to claim 5, Daugherty et al. teach a filtering means wherein unfiltered air is first captured by a set of pitot tubes, pre-filtered, and transported to the triggering and sampling subsystems (para.007). As previously described, prefilter allows the large particles to pass into main air flow (bypass air flow), while retaining the smaller particles which are captured by the prefilter at inlet flow (FIG. 7B) and passed to receiving probe, where air and particles exit the receiving probe as minor flow (product air flow).

44. With respect to claim 7, Daugherty et al. teach that a conventional programmable logic control (PLC) board (computer) sequences operations among the subsystems of system (para. 0042).

45. With respect to claim 9, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032).

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46. With respect to claim 10, Daugherty et al. teach a concentrating the particles using a conventional aerosol concentrator (para. 0032).

47. With respect to claim 11, Daugherty et al. teach a filtering means (para.007), which would purify the air.

48. With respect to claims 32, 33, 35, 37, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032).

49. With respect to claim 36, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032). Daugherty et al. further teach that the analysis subsystem can execute in real-time (para. 0011).

50. Claims 1-3, 8-11, 21-26, 30, 40 rejected under 35 U.S.C. 102(e) as being anticipated by Mariella, Jr. [US 6,787,104].

With respect to claim 1, Mariella, Jr. teaches an autonomous pathogen detection system (APDS) that utilizes immunoassays such as antibody assays or polymerase chain reaction assays with chemical detectors (column 6, lines 41-53), wherein a continuous sample of the air stream is channeled to the APDS through a conduit (aerosol collector) (column 6, lines 54-57), and a electrostatic precipitator/scrubber treats the chemical or biological agent (preparation means) (column 7, lines1-10).

51. With respect o claim 2, a continuous sample of the air stream is channeled to the APDS through a conduit (aerosol collector) (column 6, lines 54-57).

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52. With respect to claim 3, Mariella, Jr. teaches providing a filter of all of the air supply (column 10, lines 52-55), which would separate particles.

53. With respect to claims 8, 9, Mariella, Jr. teaches an autonomous pathogen detection system (APDS) that utilizes immunoassays such as antibody assays or polymerase chain reaction assays with chemical detectors (column 6, lines 41-53).

54. With respect to claim 10, Mariella, Jr. teaches a fractional pre concentrator (column 10, lines 30-34).

55. With respect to claim 11, Mariella, Jr. teaches providing a filter of all of the air supply (column 10, lines 52-55), which would separate particles.

56. With respect claim 7, Mariella, Jr. teaches an autonomous pathogen detection system (APDS) that utilizes immunoassays such as antibody assays or polymerase chain reaction assays with chemical detectors (column 6, lines 41-53). Since the system is automated, a computer would be required.

57. With respect to claim 21, Mariella, Jr. teaches an autonomous pathogen detection system (APDS) that utilizes immunoassays such as antibody assays (column 6, lines 41-53).

58. With respect to claims 22-26, 30, Mariella, Jr. teaches antibody coated beads, biotin labeled antibodies, and fluorescent labeled streptavidin system (column 7, lines 26-45), which would result in beads with fluorescently labeled antibodies (due to conjugation between biotin and streptavidin). Mariella, Jr. further teach using flow cytometry for characterization and categorization (column 7, lines 35-40).

59. With respect to claim 40, Mariella, Jr. teaches antibody coated beads, biotin labeled antibodies, and fluorescent labeled streptavidin system (column 7, lines 26-45), which would

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result in beads with fluorescently labeled antibodies (due to conjugation between biotin and streptavidin). Mariella, Jr. further teaches using flow cytometry for characterization and categorization (column 7, lines 35-40). Mariella, Jr. also teaches suspension of the particulate in liquid flow through a flow cell (column 9, lines 10-26).

Claim Rejections - 35 USC § 103

60. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

61. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daugherty et al. [US 2004/0028561] in view of Lawless et al. [US 4,923,491].

With respect to claim 6, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles in on and around mail (substance being monitored), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-hazardous particles, and an analysis subsystem for determining the composition of the biohazardous particles in the analysis sample (para. 0007). Daugherty et al. fail to teach that the collector includes a wetted-wall cyclone collector.

Lawless et al., however, teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner

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bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Lawless further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious to one of ordinary skill in the art to use the aerosol concentrator of Lawless et al. comprising a cyclone concentrator in the device of Daugherty et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

62. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

63. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641


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